IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CUBIST PHARMACEUTICALS, INC.,	)	
Plaintiff,	)	
v.	)	Civil Action No. 12-859-GMS
HOSPIRA, INC.,	)	
Defendant.	)	

DEFENDANT HOSPIRA, INC.'S ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS TO PLAINTIFF CUBIST PHARMACEUTICALS, INC.'S COMPLAINT FOR PATENT INFRINGEMENT

Defendant HOSPIRA, INC. hereby answers the Complaint filed by CUBIST PHARMACEUTICALS, INC. as follows:

AS TO THE NATURE OF ACTION

1. Hospira admits that the Complaint purports to state an action under the patent laws of the United States. Hospira further admits that Hospira filed an Abbreviated New Drug Application No. 202857 ("ANDA No. 202857") with the FDA seeking approval to manufacture and sell Daptomycin for Injection, 500 mg/ vial ("the Hospira ANDA Product"), a generic version of CUBICIN®, before the expiration of U.S. Patent No. 8,129,342 ("the '342 patent"). Hospira denies the remaining allegations in paragraph 1 of the Complaint.

AS TO THE PARTIES

2. Hospira lacks knowledge or information sufficient to admit or deny the allegations of paragraph 2 of the Complaint.

3. Hospira admits that it is a Delaware corporation with its principal place of business at 275 North Field Drive, Lake Forest, Illinois.

4. Hospira admits that it sells various generic drug products in the United States, including in Delaware. The remaining allegations contained in paragraph 4 state legal conclusions to which no responsive pleading is required. To the extent a responsive pleading is deemed to be required, Hospira denies the remaining allegations.

AS TO JURISDICTION AND VENUE

5. The allegations contained in paragraph 5 state legal conclusions to which no responsive pleading is required. To the extent a responsive pleading is deemed to be required, Hospira admits that the Court has subject matter jurisdiction over this matter under 28 U.S.C. §§ 1331 and 1338(a). Hospira denies the remaining allegations in paragraph 5 of the Complaint.

6. The allegations contained in paragraph 6 state legal conclusions to which no responsive pleading is required. To the extent a responsive pleading is deemed to be required, Hospira admits, for purposes of this action only, that venue is proper in this district under 28 U.S.C. §§ 1391 and 1400(b).

7. The allegations contained in paragraph 7 state legal conclusions to which no responsive pleading is required. To the extent a responsive pleading is deemed to be required, Hospira admits that it is incorporated under Delaware law and that it markets and sells drug products in the United States, including in Delaware. Hospira further admits that the Court has personal jurisdiction over Hospira in this action. Hospira denies the remaining allegations of paragraph 7 of the Complaint.

AS TO THE BACKGROUND

8. Hospira admits that CUBICIN® is FDA approved and that, according to its label, is a lipopeptide antibacterial indicated for the treatment of (1) complicated skin and skin structure infections; (2) *Staphylococcus aureus* bloodstream infections, including those with

right-sided infective endocarditis. Hospira denies the remaining allegations in paragraph 8 of the Complaint.

9. Hospira admits the allegations in paragraph 9 of the Complaint.

10. Hospira admits that the '342 patent states on its face that it is entitled "High Purity Lipopeptides" and further states that it was issued on March 6, 2012 and is assigned to Cubist. Hospira admits that the '342 patent is listed in the FDA Orange Book as expiring on November 28, 2020. Hospira further admits that what appears to be a copy of the '342 patent was attached to the Complaint as Exhibit A. Hospira denies the remaining allegations of paragraph 10 of the Complaint.

11. Hospira admits that the '342 patent has been listed in the FDA Orange Book in connection with CUBICIN®. The remaining allegations contained in paragraph 11 state legal conclusions to which no responsive pleading is required. To the extent a responsive pleading is deemed to be required, Hospira denies the remaining allegations.

12. Hospira admits the allegations of paragraph 12 of the Complaint.

13. Hospira admits the allegations of paragraph 13 of the Complaint.

14. Hospira admits that this action appears to have been commenced within forty-five days of Cubist's receipt of Hospira's Notice Letter.

AS TO THE CLAIM FOR RELIEF

INFRINGEMENT OF U.S. PATENT NO. 8,129,342

15. In response to the allegations contained in paragraph 15 of the Complaint, Hospira realleges its responses to paragraphs 1-14 as if fully set forth herein.

16. The allegations contained in paragraph 16 state legal conclusions to which no responsive pleading is required. To the extent a responsive pleading is deemed to be required, Hospira denies the allegations of paragraph 16 of the Complaint.

17. The allegations contained in paragraph 17 state legal conclusions to which no responsive pleading is required. To the extent a responsive pleading is deemed to be required, Hospira admits that the submission of Hospira's ANDA with a paragraph IV certification to the '342 patent is considered a technical act of infringement under 35 U.S.C. § 271(e)(2)(A) for purposes of creating a case or controversy between the parties so that the Court has jurisdiction over this matter. Hospira denies the remaining allegations of paragraph 17 of the Complaint.

18. Hospira denies the allegations of paragraph 18 of the Complaint.

19. Hospira denies the allegations of paragraph 19 of the Complaint.

AS TO THE PRAYER FOR RELIEF

Hospira denies that Plaintiff Cubist is entitled to the judgment and relief prayed for in paragraphs (a) through (f) of the Complaint or to any relief whatsoever.

HOSPIRA'S AFFIRMATIVE DEFENSES

FIRST DEFENSE

The manufacture, use, offer for sale, sale or importation of the Hospira ANDA Product that is the subject of ANDA No. 202587 does not and will not infringe one or more claims of the '342 patent, either literally or under the doctrine of equivalents.

SECOND DEFENSE

The claims of the '342 patent are invalid under 35 U.S.C. § 102 and/or § 103 at least for the reasons stated in Hospira's Notice Letter dated May 31, 2012, referenced in paragraph 12 of this Complaint.

THIRD DEFENSE

The claims of the '342 patent are invalid for failing to meet the requirements of 35 U.S.C. § 112, including by failing to adequately describe the full scope of the claimed invention and/or enable a person of ordinary skill in the art to use the claimed invention.

FOURTH DEFENSE

To the extent the Complaint purports to allege that this case is exceptional within the meaning of 35 U.S.C. § 285 and seeks an award of attorneys fees, the Complaint fails to state a claim upon which relief can be granted.

FIFTH DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the equitable doctrines of estoppel, waiver, and unclean hands.

COUNTERCLAIMS FOR DECLARATORY JUDGMENT

Defendant and Counterclaim Plaintiff Hospira, Inc., by way of counterclaim against Plaintiff and Counterclaim Defendant Cubist Pharmaceuticals, Inc., alleges as follows:

THE PARTIES

1. Hospira is a corporation organized and existing under the laws of Delaware with its principal place of business at 275 N. Field Drive, Lake Forest, Illinois 60045.

2. On information and belief, and according to its Complaint filed in this action, Cubist is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 65 Hayden Avenue, Lexington, Massachusetts.

JURISDICTION AND VENUE

3. These counterclaims arise under the Patent Act of 1952, 35 U.S.C. §§ 1 *et seq.*,

and under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq*. This Court has subject matter jurisdiction to hear this action under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

4. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b).

BACKGROUND

5. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.,* as amended by the Hatch-Waxman Amendments, sets forth the rules that the U.S. Food & Drug Administration ("FDA") follows when considering the approval of applications for both brand-name and generic drugs.

6. Under the Hatch-Waxman Amendments, an applicant seeking to market a new brand-name drug must prepare a New Drug Application ("NDA") for consideration by the FDA. *See* 21 U.S.C. § 355.

7. An NDA must include, among other things, the patent number of any patent that claims the drug or a method of using such drug, for which the applicant submitted the NDA and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. *See* 21 U.S.C. § 355(b)(1) and (c)(2); 21 C.F.R. §§ 314.53(b) and (c)(2).

8. Upon approval of the NDA, the FDA publishes patent information for the approved drug in its publication, *Approved Drug Products with Therapeutic Equivalence Evaluation* ("Orange Book"). *See* 21 U.S.C. § 355(j)(7)(A)(iii).

9. Generic drugs are versions of brand-name prescription drugs that have been shown to be "bioequivalent" to the listed reference NDA drug approved by the FDA. *See* 21 U.S.C. § 355(j)(4)(F). Under the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Amendments, *see* Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156 and 271(e)), a generic manufacturer submits

what is called an Abbreviated New Drug Application to obtain approval to sell a generic drug.

10. When filing an ANDA seeking approval of a generic version of a drug listed in the Orange Book, the ANDA applicant must also "certify" that any patent information listed in the Orange Book does not preclude FDA approval of the ANDA applicant's generic version of the drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12).

11. A so-called "paragraph IV" certification asserts that the listed patent is invalid, unenforceable, and/or will not be infringed and, on that basis, seeks FDA approval of the generic product before patent expiration. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

12. Hospira filed ANDA No. 202587 with the FDA under 21 U.S.C. § 355(j) to obtain approval to engage in the commercial manufacture, use or sale of a generic pharmaceutical product, Daptomycin for Injection, 500 mg/vial, that is related to the daptomycin product that is the subject of NDA No. 021572 and is commercially known as CUBICIN®. Cubist is identified in FDA records as the approval holder of NDA No. 021572.

13. Hospira's ANDA No. 202587 included a "paragraph IV" certification under 21 U.S.C. §355(j)(2)(A)(vii)(IV) with respect to U.S. Patent No. 8,129,342, among others, and alleged that the '342 patent is invalid, unenforceable, and/or would not be infringed by the commercial manufacture, use, or sale of the proposed daptomycin drug product described by Hospira's ANDA No. 202587.

The '342 Patent

14. The '342 patent was issued on March 6, 2012, to Kelleher et al., and assigned to Cubist. On information and belief, Cubist is the current owner of the '342 patent, which is scheduled to expire no later than November 28, 2020.

15. Cubist listed the '342 patent in the Orange Book in connection with CUBICIN®.

16. To have the '342 patent listed in the Orange Book, the law required Cubist to certify to the FDA, under oath, that the '342 patent claims the "drug" daptomycin or a "method of using" daptomycin and is a patent for which a claim of patent infringement could reasonably be asserted against an unauthorized party.

17. By bringing suit against Hospira, Cubist has taken active steps to block Hospira's attempt to launch a generic daptomycin drug product or products.

18. The claims of the '342 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, offer for sale, or importation of Hospira's proposed daptomycin drug product(s).

19. Because of the foregoing facts, there is a real, substantial, immediate, and continuing justiciable controversy between Hospira and Cubist as to liability for infringement of, and validity and/or enforceability of, the '342 patent.

COUNTERCLAIM I

(Declaration of Invalidity of the '342 Patent)

20. Hospira realleges and incorporates by reference the allegations contained in the previous paragraphs of the Counterclaims as if set forth here.

21. The claims of the '342 patent are invalid under the provisions of 35 U.S.C. § 102 and/or § 103 for at least the reasons stated in Hospira's Notice Letter dated May 31, 2012, referenced in paragraph 12 of this Complaint.

22. Specifically, the claims of the '342 patent are invalid as anticipated and/or obvious over at least the following prior art: (1) U.S. Patent. No. 4,874,843; (2) Protein Purification: Principles, High Resolution Methods, and Applications (Janson J. and Ryden L. ed., John Wiley & Sons, Inc., 1998); (3) S-C Lin and H-J Jiang, "Recovery and Purification of

the Lipopeptide Biosurfactant of Bacillus subtilis by Ultrafiltration," *Biotechnology Techniques,* 11(6): 413-416; (4) Shaw, D.J., "Liquid-Gas and Liquid-Liquid Interfaces," Introduction to Colloid and Surface Chemistry, pp. 64-114 (Butterworth-Heinemann Ltd.); (5) Remington: The Science and Practice of Pharmacy (19th ed., Mack Publishing Company, 1995); (6) Harrisons Principles of Internal Medicine (14th ed. Fauci a. *et al.*, ed. McGraw-Hill, 1998); and (7) Sexton D. *et al.*, "The Use of Daptomycin, a Lipopeptide Antibiotic, in the Treatment of Gram Positive Infections in Man," Interscience Conference on Antimicrobial Agents and Chemotherapy, p. 932 (1998).

23. The claims of the '342 patent are invalid for failing to meet the requirements of 35 U.S.C. § 112, including by failing to adequately describe the full scope of the claimed invention and/or enabling a person having ordinary skill in the art to use the claimed invention.

24. Hospira is entitled to a declaratory judgment that the claims of the '342 patent are invalid.

COUNTERCLAIM II

(Declaration of Non-Infringement of the '342 Patent)

26. Hospira realleges and incorporates by reference the allegations contained in the previous paragraphs of the Counterclaims as if set forth here.

27. The manufacture, use, sale, offer for sale, or importation into the U.S. of Hospira's proposed daptomycin products that are the subject of ANDA No. 202587 would not infringe any valid and/or enforceable claim of the '342 patent.

28. Hospira is entitled to a judicial declaration that its proposed daptomycin products that are the subject of ANDA No. 202587 would not infringe any valid and/or enforceable claim of the '342 patent.

HOSPIRA'S PRAYER FOR RELIEF

WHEREFORE, Hospira, Inc. respectfully prays that the Court grant the following relief:

A. Declaring that Hospira's proposed Daptomycin for Injection (500 mg/ vial) product does not, and would not if commercially manufactured, used, sold, offered for sale, or imported into the United States, infringe any valid and enforceable claim of U.S. Patent No. 8,129,342;

B. Declaring that Hospira, Inc. has not infringed any valid and enforceable claim of U.S. Patent No. 8,129,342 and is not liable for infringement;

C. Declaring that the claims of U.S. Patent No. 8,129,342 are invalid;

D. Declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding to Hospira attorneys' fees and expenses in this action;

E. Awarding Hospira costs; and

F. Awarding Hospira such other and further relief as the Court may deem just, proper and equitable under the circumstances.

Dated: July 23, 2012

PHILLIPS, GOLDMAN & SPENCE, P.A.

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